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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,812	03/28/2001	Biaoyang Lin	P-IS 4373	5002

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 04/09/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/821,812

Applicant(s)

LIN, BIAOYANG

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-71 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-3, drawn to a nucleic acid molecule of SEQ ID NO:1, and fragments thereof, classified in class 536, subclass 23.1.

Groups II. Claims 4-7, drawn to a method of diagnosing a prostate neoplastic condition, comprising determining the expression level of ARP1 mRNA, classified in class 435, subclass 6.

Group III. Claims 4-7, drawn to a method of predicting susceptibility to a prostate neoplastic condition, comprising determining the expression level of ARP1 mRNA, classified in class 435, subclass 6.

Group IV. Claim 8, drawn to a method for treating a prostate neoplastic condition, comprising administering an ARP1 regulatory agent, classified in class 424, subclass 2.

Group V. Claims 9-11, drawn to a nucleic acid molecule of SEQ ID NO: 2, and fragments thereof, classified in class 536, subclass 23.1.

Group VI. Claims 12-15, drawn to drawn to a method of diagnosing a prostate neoplastic condition, comprising determining the expression level of ARP2 mRNA, classified in class 435, subclass 6.

Group VII. Claims 12, drawn to a method of predicting susceptibility to a prostate neoplastic condition, comprising determining the expression level of ARP2 mRNA, classified in class 435, subclass 6.

Group VIII. Claim 16, drawn to a method for treating a prostate neoplastic condition, comprising administering an ARP 2 regulatory agent, classified in class 424, subclass 2.

Group IX. Claims 17-19, drawn to a nucleic acid molecule of SEQ ID NO: 4, or a nucleic sequence encoding a variant of a polypeptide of SEQ ID NO:5, classified in class 536, subclass 23.1.

Group X. Claims 20-23, drawn to a method of diagnosing a prostate neoplastic condition, comprising determining the expression level of ARP3 mRNA, classified in class 435, subclass 6.

Group XI. Claims 20-23, drawn to a method of predicting susceptibility to a prostate neoplastic condition, comprising determining the expression level of ARP3 mRNA, classified in class 435, subclass 6.

Group XII. Claims 24-26, drawn to a polypeptide of SEQ ID NO:5, and variants thereof, classified in class 424, subclass 2.

Group XIII. Claims 27-28, drawn to a binding agent that selectively binds a polypeptide having at least 45% amino acid identity with SEQ ID NO:5, classified in class 530, subclass 387.1.

Group XIV. Claims 29-32, drawn to a method of diagnosing a prostate neoplastic condition, comprising determining the expression level of ARP3 polypeptide, classified in class 435, subclass 7.1.

Group XV. Claims 29-32, drawn to a method of predicting susceptibility to a prostate neoplastic condition, comprising determining the expression level of ARP3 polypeptide, classified in class 435, subclass 7.1.

Group XVI. Claims 33, drawn to a method for treating a prostate neoplastic condition, comprising administering an ARP3 regulatory agent, classified in class 424, subclass 2.

Group XVII. Claims 34-38, drawn to a nucleic acid molecule of SEQ ID NO: 6, or a nucleic sequence encoding a variant of a polypeptide of SEQ ID NO:7, classified in class 536, subclass 23.1.

Group XVIII. Claims 39-42, drawn to a method of diagnosing a prostate neoplastic condition, comprising determining the expression level of ARP4 mRNA, classified in class 435, subclass 6.

Group XIX. Claims 39-42, drawn to a method of predicting susceptibility to a prostate neoplastic condition, comprising determining the expression level of ARP4 mRNA, classified in class 435, subclass 6.

Group XX. Claims 43-45, drawn to a polypeptide of SEQ ID NO:7, and variants thereof, classified in class 530, subclass 350.

Group XXI. Claims 46-47, drawn to a binding agent that selectively binds a polypeptide having at least 45% amino acid identity with SEQ ID NO:7, classified in class 530, subclass 387.1.

Group XXII. Claims 48-51, drawn to a method of diagnosing a prostate neoplastic condition, comprising determining the expression level of ARP4 polypeptide, classified in class 435, subclass 7.1.

Group XXIII. Claims 48-51, drawn to a method of predicting susceptibility to a prostate neoplastic condition, comprising determining the expression level of ARP4 polypeptide, classified in class 435, subclass 7.1.

Group XXIV. Claim 52, drawn to a method for treating a prostate neoplastic condition, comprising administering an ARP4 regulatory agent, classified in class 424, subclass 2.

Group XXV. Claims 53-57, drawn to a nucleic acid molecule of SEQ ID NO: 8, or a nucleic sequence encoding a variant of a polypeptide of SEQ ID NO:7, classified in class 536, subclass 23.1.

Group XXVI. Claims 58-61, drawn to a method of diagnosing a prostate neoplastic condition, comprising determining the expression level of ARP5 mRNA, classified in class 435, subclass 6.

Group XXVII. Claims 58-61, drawn to a method of predicting susceptibility to a prostate neoplastic condition, comprising determining the expression level of ARP5 mRNA, classified in class 435, subclass 6.

Group XXVIII. Claims 62-64, drawn to a polypeptide of SEQ ID NO:9, and variants thereof, classified in class 530, subclass 350.

Group XXIX. Claims 65-66, drawn to a binding agent that selectively binds a polypeptide having at least 45% amino acid identity with SEQ ID NO:9, classified in class 530, subclass 387.1.

Group XXX. Claims 67-70, drawn to a method of diagnosing a prostate neoplastic condition, comprising determining the expression level of ARP5 polypeptide, classified in class 435, subclass 7.1.

Group XXXI. Claims 67-70, drawn to a method of predicting susceptibility to a prostate neoplastic condition, comprising determining the expression level of ARP5 polypeptide, classified in class 435, subclass 7.1.

Group XXXII. Claim 71, drawn to a method for treating a prostate neoplastic condition, comprising administering an ARP5 regulatory agent, classified in class 424, subclass 2.

In addition, upon election of any of groups II, III, VI, VII, X, XI, XIV, XV, XVIII, XIX, XXII, XXIII, XXVI, XXVII, XXX, XXXI, further election of the following species is required:

Prostate tissue, blood, urine and semen.

The inventions are distinct, each from each other because of the following reasons:

Inventions (I, V, IX, XII, XIII, XVII, XX, XXI, XXV, XXVIII, XXIX) and (II-IV, VI-VIII, X-XI, XIV-XVI, XVIII-XIX, XXII-XXIV, XXVI-XXVII, XXX-XXXII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the

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following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; and an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases.

The products of groups (I, V, IX, XII, XIII, XVII, XX, XXI, XXV, XXVIII, XXIX are patentably distinct, because they are drawn to entirely different biochemicals , having different structures, biological properties and activities that are not interchangeable and cannot be used in place of each other.

The methods of groups (II-IV, VI-VIII, X-XI, XIV-XVI, XVIII-XIX, XXII-XXIV, XXVI-XXVII, XXX-XXXII) are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species prostate tissue, blood, urine and semen are distinct because they have different characteristics and properties.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

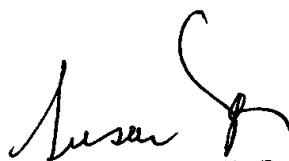
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accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.



SUSAN UNGAR, PH.D
PRIMARY EXAMINER

MINH TAM DAVIS

April 8, 2002